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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,454	09/17/2003	Mark L. Jenson	760-68	4333
23869	7590	12/01/2005	EXAMINER	
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE SYOSSET, NY 11791			GHERBI, SUZETTE JAIME J	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/664,454

Applicant(s)

JENSON, MARK L.

Examiner

Suzette J. Gherbi

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 28-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-22 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoganson et al. 2003/0074049. Hoganson et al. discloses the claims as currently presented comprising: a first polymeric liner; a second polymeric liner (see 0078 which states that the cover/liner may be located on the exterior of the stent framework and on the interior); an intermediate structural member (10) interposed between the first and second liners wherein the structural member is defined by solid segments (the struts) and openings (which are the interstitial spaces) there between. However Hoganson et al. does not utilize the term "bonded" when referring to joining the first and second covers/liners as shown in 2c. Hoganson et al. does however state in section [0078] that the covers may be located **in the interstitial spaces between the portions or sections "24"**. It would have been obvious to one having ordinary skill in the art that because the inner and outer covers are "between" the spaces and frame work that they meet the broad term "bonded" (which is not defined by the applicant's specification). It is also obvious to one having ordinary skill in the art that because the

covers/liners have drugs incorporated within them [0105] that when they are fixed between the interstitial spaces of the framework then a "pocket" is formed around the struts of the stent. See section [0066] for stent details; [0105-0116] for drug/agent details; [0079] for varying the porosity; and [0071- 0076] tables 1 and 2 for types of polymers utilized.

3. Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoganson et al. in view of Golds et al. 6,001,125. Hoganson et al. has been disclosed above however Hoganson et al. does not specify internodal distance. Golds et al. teach methods of manufacturing ePTFE with internodal distances of less than 40 microns (see col. 3, lines 55-60 and col. 4, lines 66-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the polymer layers of Hoganson et al. and manufacture the internodal distance of less than 40 microns because Hoganson discloses that the polymer tube is made from ePTFE and by creating the nodes within this range would provide superior radial tensile and suture retention strengths which are required for vascular grafts.

Response to Arguments

4. Applicant's arguments filed 9/12/05 have been fully considered but they are not persuasive. Applicant has amended the specification to correct prior 112 rejections and grammatical errors. Applicant further contends that Hoganson does not disclose a

covered stent with a first polymeric liner bonded to a second polymeric liner through the openings so as to form a pocket. The examiner disagrees and feels that the term "bond" in its broadest interpretation has been met by the disclosure of Hoganson because as pointed out above Hoganson's covers can be placed between the interstitial spaces of the framework therefore the framework is helping to "bond" the first and second liners/covers together. Further Hoganson later discloses that many methods can be utilized to secure the covers/liners to the framework including heating and radial compression and because an inner and exterior liner are utilized in figure 2c it is obvious that these liners will bond between the spaces if a heat/shrink process is utilized. Applicant further contends that there are not drugs/bioactive substances located in a pocket. This argument has been addressed above.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

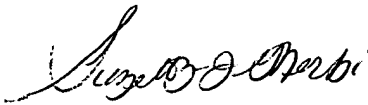
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

7. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

8. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Suzette J-J Gherbi
28 November 2005

